

### **DETAILED ACTION**

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are pending in this application.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on September 30, 2008 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Action Summary***

Any rejections of record that are not repeated below are considered withdrawn.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saidi et al. (US 6,241,969) in view of Karlsson et al. (US 2002/0065256).

Applicants claim a fluticasone composition comprising particles of fluticasone having a particles size of less than 900 nm and at least one surface stabilizer.

***Determination of the scope and content of the prior art***

**(MPEP §2141.01)**

Saidi et al. teach a composition containing a corticosteroid for treatment of ailments and diseases of the respiratory tract by way of nasal and pulmonary administration (abstract). Column 6, lines 8-20 teaches examples of the corticosteroids that can be used in the invention including fluticasone. Column 7, line 54 teaches that the aqueous phase of the composition is comprised of water. Examples 1-4 teach that the diluted corticosteroid compositions are sterilized by passing them through a 0.22 micron sterile filter.

***Ascertainment of the difference between the prior art and the claims***

**(MPEP §2141.02)**

Saidi et al. do not teach the particles comprising a surface stabilizer as claimed. It is for this that Karlsson et al is joined.

Karlsson et al. teach a process for sterilization of a powdered form of a glucocorticosteroid wherein the glucocorticosteroids are used in the treatment of allergic and/or inflammatory conditions of the nose or lungs (abstract). ¶ [0016] teach examples of the glucocorticosteroid used in the composition i.e. fluticasone (e.g. as propionate). ¶ [0031] teach the use of the composition. ¶ [0033] teaches the use of pharmaceutically acceptable additives. ¶ [0035] teach suitable surfactants that can be employed in the composition, mention being made to Tyloxapol™ and polyoxyethylene alkyl ethers. ¶ [0036] teach the concentration of the surfactant at about 0.002 to 2% w/w. ¶ [0042] teach the percentage of particles having a specific particle size. ¶ [0044] teach that a suspension containing the active agent and additional ingredients can be produced by sterile filtration. The several examples teach the active agent in concentrations as claimed by applicant.

***Finding of prima facie obviousness***

***Rational and Motivation (MPEP §2142-2143)***

As mention above, Saidi et al. do not teach a surface stabilizer, to solve this deficiency Karlsson et al. is relied upon. ¶ [0034] teach that in order to obtain an efficient dispersion of the glucocorticosteroid particles in the suspension, a surfactant

may be used and that they may also function as stabilizing agents. ¶ [0035] teach examples of surfactants which can be employed in composition. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Karlsson et al. of using a surfactant as a stabilizing agent for the particles in the invention of Saidi et al. to arrive at the claimed invention. The expected result of the combination of reference would be a composition comprising a solution of corticosteroids (i.e. fluticasone) particles and a surface stabilizer that sterilized by filtration through a 0.2 micron filter.

### ***Conclusion***

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 remain rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Konata M. George/  
Primary Examiner, Art Unit 1616